

## **EXHIBIT B**

### **GOVERNANCE ENHANCEMENTS AND CHANGES**

As set forth below, the Company's corporate governance and compliance organizational structure, policies, protocols and procedures have been enhanced and changed since early 2010. The enhancements and changes were implemented and adopted as a consequence of internal and external considerations, including (i) the Company's continual review and evaluation of its policies, processes and procedures, (ii) the underlying conduct and government actions and investigations referenced in the Derivative Actions, (iii) the Derivative Actions, and (iv) the Special Committee investigation and findings. During the Settlement Commitment Term, the Company may make modifications that are consistent with the objectives of the Settlement to the provisions set forth in this Exhibit B.

#### **I. BOARD LEVEL**

##### **A. Board Oversight of J&J's Enterprise Risk Management (ERM) Framework.**

**1. Board Responsibility for ERM Framework.** The Board has oversight responsibility for the ERM framework (described below, see Section II.A.). The Board meets at regular intervals with key members of management, who have primary responsibility for risk management within their areas.

**2. Board Reports.** The Board also receives regular reports on aspects of the Company's risk management from senior representatives of the Company's independent auditor. The Audit Committee meets in private sessions with the Chief Finance Officer (CFO), General Counsel, J&J Chief Compliance Officer (J&J CCO), VP of Corporate Internal Audit (VP-CIA), and representatives of the independent auditor regarding aspects of risk management. The Board also met with the J&J Chief Quality Officer (J&J CQO) every quarter in 2011. Certain of this reporting will now be made to the

Regulatory, Compliance & Government Affairs Committee (“RCGC”) in accordance with its Charter and Operating Procedure.

**B. Regulatory, Compliance & Government Affairs Committee**

Based upon the work of the Special Committee, the Board authorized the creation of a board committee to oversee the regulatory compliance and quality programs of the Company. In accordance with that authorization, the Board created the Regulatory, Compliance & Government Affairs Committee. The Charter and Operating Procedures for that committee were negotiated and adopted pursuant to this Settlement and are set out in Exhibit A to the Stipulation of Settlement.

**II. MANAGEMENT LEVEL**

**A. J&J’s Enterprise Risk Management Framework.** J&J had previously instituted an overarching ERM framework for the entire J&J enterprise, including the business units and corporate functions.

**1. J&J’s Consolidated ERM Process.** Under the ERM Framework, ERM at J&J is a consolidated process through which the Board, management, and other J&J personnel apply a common risk management approach across the enterprise, with identified ERM components, such as objective setting, risk identification and assessment, risk response and control activities, and communication and monitoring. ERM components are applied across J&J’s business units and also across a number of defined risk function areas.

**2. Risk Function Leadership Teams.** Each risk function area has a leadership team.

a. Individual business units and risk function areas are responsible for performing risk assessments and audits to identify and assess trends and emerging risks, and for developing remediation plans when necessary. The effectiveness of action plans is monitored through review of metrics as part of ongoing management reviews.

b. Each business unit and each risk function area communicates identified risks and the response strategies to its leadership team, and will escalate issues as necessary and appropriate to its respective Executive Committee member, or directly to the Audit Committee or the RCGC, as appropriate.

**3. Enhancements to J&J's ERM Framework.** During the pendency of the Derivative Actions, J&J's ERM Framework has been enhanced to reflect, inter alia, the following organizational and process changes:

a. **Streamlined Escalation Procedure.** J&J has established requirements for escalation applicable to all J&J operating companies and businesses. Potential violations of law or of J&J policies are identified in multiple ways. For example, operating companies identify issues when testing and monitoring internal controls over compliance policies (such as the Foreign Corrupt Practices Act (FCPA), Quality, and Safety). Also, issues are identified through hotline calls or other reporting by employees. Pursuant to J&J's escalation policy, any covered issue must be reported within three business days to the VP-CIA. The VP-CIA acts as the focal point for receiving reports, bringing allegations to the Triage Committee for review, monitoring the timely investigation and resolution of potential violations, and reporting on such matters

to senior management, and where appropriate, to the Audit Committee. Where appropriate, the VP-CIA will make such reports to the RCGC in accordance with its Charter and Operating Procedure.

b. **Consolidated Quality and Supply Chain Functions.** J&J has implemented a company-wide plan to more effectively coordinate Quality and Supply Chain (described below), while also reducing complexity and risk.

**B. Supply Chain.**

1. **J&J Supply Chain (JJSC).** J&J has implemented a global Supply Chain function to carry out procurement, manufacturing, and supply chain quality assurance and distribution for all of J&J's businesses. The JJSC includes a worldwide network of manufacturing sites, external manufacturers, and distribution centers. Enterprise and Sector Supply Chain leaders ensure that appropriate investments are made, ensure escalation of significant events and risks, monitor enterprise trends and establish new risk management approaches when necessary. The Vice President, J&J Supply Chain has reported to a J&J Vice Chairman in the past, and will continue to report to a direct report of the CEO. The Vice President, J&J Supply Chain will provide quarterly in-person reporting to the CEO in a private session.

The Vice President, J&J Supply Chain provides an annual report to the full Board and to the Audit Committee related to Supply Chain issues. That report will now be made to the RCGC in accordance with its Charter and Operating Procedure.

2. **Supply Chain Risk Management.** The Supply Chain Leadership Team uses dashboard metrics, risk assessments, business continuity planning exercises, and other inputs to identify patterns and trends, and highlight risks for follow-up actions.

Risk management is primarily the responsibility of the business units, with shared responsibility with JJSC for oversight and risk mitigation. Critical metrics are reported to the Supply Chain Leadership Team, to the management Compliance Committee, or to the appropriate Board committee. Reporting formerly made to the Audit Committee will now be made to the RCGC in accordance with its Charter and Operating Procedure.

**C. Quality.**

**1. Single Framework for Quality and Compliance.** A key aspect of the new J&J Supply Chain operating model is the creation of a single framework for Quality & Compliance across all of J&J's operating companies. This single framework is intended to standardize processes in the Company's quality systems and provide greater oversight in order to reduce both complexity and risk in the area of quality.

**2. The J&J Chief Quality Officer (J&J CQO).** The J&J CQO reports to the Vice President, Supply Chain, and makes quarterly reports to the Audit Committee or the Board. The J&J CQO will now make such reports to the RCGC in accordance with its Charter and Operating Procedure.

**3. J&J CQO Responsibilities.** The J&J CQO has oversight of quality throughout the Enterprise.

a. All staff in Quality and Regulatory Compliance functions worldwide have a reporting relationship to the J&J CQO.

b. The J&J CQO sets Enterprise Quality Policy and Standards to promote consistency and uniformity in quality requirements.

c. The J&J CQO reports quality and regulatory compliance metrics and issues to Executive Management.

d. The J&J CQO has established and will maintain an Enterprise Regulatory Compliance function to provide independent oversight of the effectiveness of J&J's Quality systems.

**4. Sector CQO Responsibilities.** J&J has appointed Chief Quality Officers for each business Sector. Sector CQOs report to the J&J CQO.

a. Sector CQOs are responsible for governance of quality and regulatory compliance activities at R&D companies, marketing and local operating companies, and JJSC manufacturing sites.

b. Sector CQOs are responsible to implement and oversee a Quality and Regulatory Compliance strategy.

c. Sector CQOs are required to establish a Regulatory Compliance function to provide independent oversight of the effectiveness of the Sector's Quality systems. This Sector oversight program is independent of the Enterprise oversight program.

d. Sector CQOs are required to communicate risks to the Sector management and to the J&J CQO as appropriate.

**5. The J&J Quality Policy.** The J&J Quality Policy is the top-level Quality document and defines Quality & Compliance requirements throughout the enterprise. The current version of the Quality Policy is POL-001, issued on March 31, 2011. The Quality Policy requires, among other things, that every J&J company establish an independent quality function with the necessary resources, establish an internal audit program for its quality system, establish a comprehensive system for handling product complaints and reporting adverse events, document the process for investigating and

controlling nonconformities, establish procedures for the conduct of field action activities, and establish processes for corrective actions and preventive actions.

**6. J&J Standards.** J&J Standards set specific requirements in quality and technical areas that are uniform throughout the Enterprise. J&J Standards are mandatory and applicable to every J&J company. Sector Standards promulgated pursuant to J&J Standards must be consistent with those J&J Standards. Individual J&J sites align procedures where needed to assure consistency with J&J and Sector Standards. The following new enterprise-wide quality Standards have been implemented at the Company in 2011:

a. Management Review (STD-001), implemented on June 30, 2011, sets requirements for management review processes at company, Sector, and Enterprise levels, identifies who needs to be present at management reviews and what needs to be reviewed, and includes review of metrics in a number of areas.

b. Escalation of Quality and Regulatory Compliance Issues (STD-002), implemented on June 30, 2011, sets requirements for processes at every J&J company to escalate information on quality issues to the appropriate management level. These requirements are to ensure that information on all significant quality and regulatory compliance issues is escalated in a timely manner, including the escalation of certain types of issues to identified persons within one business day.

c. Field Action (STD-003), implemented on June 30, 2011, requires every J&J company to establish field action procedures. A field action is any correction, corrective action, or preventive action that is implemented with respect to a product that has left J&J's control, i.e., actions such as alerts to healthcare

providers and recalls. The Field Action Standard establishes parameters for Quality Review Board proceedings throughout J&J. Specifically, pursuant to the Field Action Standard, a formally constituted Quality Review Board must evaluate product quality issues in the field and determine whether field action (removal or field correction) is required, and the scope and depth of that action.

d. Pallet Management (STD-005), implemented on September 1, 2011, has the purpose of preventing pallets from adversely impacting the quality of the materials and products that are stored on them, and provides for the elimination of wood pallets in a number of applications by June 2012.

e. Additional enterprise-wide Quality Standards are being developed in 2012, including related to Corrective and Preventive Action (CAPA), Training, and Procurement Controls/Supplier Quality.

**7. Additional Risk Management Provisions.** J&J has implemented a coordinated mandatory two-tier audit program between Enterprise and Sector. These two groups work in a coordinated fashion, to assess compliance from a top-down and a bottom-up approach. Regulatory outreach and intelligence teams are established for emerging trends. Enterprise oversight is maintained by an Enterprise Regulatory Compliance Group that reports directly to the J&J CQO. This group has been realigned and expanded to improve regulatory compliance of operating companies by providing robust, mandatory independent assessments.

a. The Enterprise Regulatory Compliance Group's independent audit program will evaluate, on a three-year cycle, all of J&J's internal manufacturing plants, operating companies with regulated quality activities, and distribution



centers that are inspected by health authorities. Higher risk sites will be audited more frequently.

b. The audit program, commenced in 2011, is designed to audit more than 100 sites in any given year going forward.

c. Significant issues are escalated and reported via metrics. Significant inspections will have independent review of responses and follow-up.

d. The Enterprise Regulatory Compliance Group reports directly to the J&J CQO, who is outside of the business units and the Sectors, assuring independent oversight of Quality and Regulatory Compliance at J&J, apart from Sector or Supply Chain Quality & Compliance activities.

e. Pursuant to SOP-027, effective June 21, 2011, J&J established a group within the Enterprise Regulatory Compliance function to provide independent oversight by corporate-level management of McNeil's activities under the Consent Decree of Permanent Injunction with the U.S. FDA for manufacturing facilities operated by the McNeil Consumer Healthcare Division of McNeil-PPC, Inc. in Las Piedras, PR, Fort Washington, PA, and Lancaster, PA.

**D. Health Care Compliance.**

**1. Health Care Compliance and Privacy (HCC&P).** J&J's integrated, enterprise-wide HCC&P organization is responsible for issues related to the FCPA and other anti-corruption laws and regulations, False Claims Act, Anti-Kickback Statute, and off-label promotion, as well as the implementation of corporate integrity and deferred prosecution agreements. The HCC&P organization is responsible for providing

infrastructure and guidance to effectively prevent and/or detect violations of law, regulations, policies, and codes of conduct.

**2. The J&J Chief Compliance Officer (J&J CCO).** The J&J CCO reported to a J&J Vice Chairman in the past, and will continue to report to a direct report of the CEO. The J&J CCO will provide quarterly in-person reporting to the CEO in a private session. The J&J CCO made quarterly reports to the Audit Committee. The J&J CCO will now make such reports to the RCGC Committee in accordance with its Charter and Operating Procedure.

**3. Sector Health Care Compliance (HCC) Officers.** HCC Officers are appointed for each Sector and for geographic regions. Within the Sectors, there are HCC Officers embedded in each of the business units. All of the HCC Officers report through the independent HCC&P organization, not through the business units. Compliance issues are regularly reported at operating company management board meetings and at the Sector management level.

**4. HCC Risk Management.** HCC&P uses a number of tools as compliance indicators, including risk assessments, business profiles, ongoing testing and monitoring, hotline metrics, and the results of audits performed by Corporate Internal Audit. HCC&P conducts testing and monitoring at the business units in accordance with a risk-based testing plan.

a. The J&J CCO chairs the Triage Committee, which has membership from Corporate Internal Audit, the Law Department, Global Security and Human Resources. Twice weekly, the Triage Committee reviews sensitive issue allegations and the progress of related investigations.

b. Key risk and compliance issues are reported to the management Compliance Committee, Executive Committee, and Audit Committee on an ongoing basis by the J&J CCO, at regular intervals or as needed. The J&J CCO will now report such issues to the RCGC in accordance with its Charter and Operating Procedure.

c. In connection with the reorganization of HCC, the management Compliance Committee expanded and clarified its mission:

i. The Compliance Committee is composed of the J&J CCO, the Integration Leader, the Sector HCC Officers, VP-CIA, the Corporate Secretary, the J&J CQO, and representatives from the Law Department, Human Resources, and Finance.

ii. The responsibilities of the Compliance Committee include, inter alia: (1) to facilitate the exchange of expertise and knowledge among the represented Compliance functions; (2) to review and provide input into reports to the Sector management, Executive Committee, Audit Committee, going forward the RCGC, and the Board; (3) to escalate Compliance issues to the relevant management or governing body; (4) to review and discuss emerging Compliance concerns and recommend actions; and (5) to provide input into J&J's Enterprise Risk Management.

iii. The Compliance Committee has quarterly meetings in preparation for Sector management, Executive Committee, Audit Committee meetings, and going forward the RCGC meetings.